

Rapid Diagnosis of Tuberculosis

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Rapid diagnosis of active tuberculosis to minimize associated mortality, and facilitate timely countermeasures

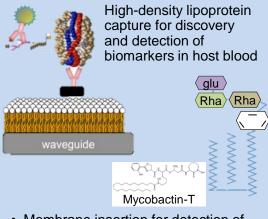
BACKGROUND & MOTIVATION

Current diagnosis of active tuberculosis is inadequate, especially with HIV co-infection in endemic populations



INNOVATION

Detection of a suite of pathogen biomarkers using novel strategies



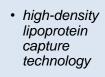
· Membrane insertion for detection of monomeric amphiphiles, application to small molecules

DESCRIPTION

A novel pathogen biomarker-based assay for the diagnosis of active tuberculosis and validated it in a blinded clinical study.

The approach uses three different Detection in TB patients assays to detect but not in controls in a pathogen double-blinded study biomarkers directly from host urine and blood. sandwich immunoassays

 membrane insertion



Waveguide with phospholipid bilayer

Antigen Insertion

fluorescently labeled antibody

Detection with a

TB Infected

Controls

8 9 10 11 12 13 14

Potentially extendable to all classes of pathogen biomarkers. For amphiphiles, approach optimization may vary depending on host carrier molecules and stability in the bilayer. Optimization may be required for some biomarkers.

TRL 3: New assay methods developed and proof of concept demonstrated: HDL capture and membrane insertion.

Three full system sensor prototypes developed and tested with sandwich immunoassays.

UNCLASSIFIED

ANTICIPATED IMPACT

Rapid, early diagnosis of active tuberculosis, extendable to all pathogens

Start to finish diagnostics:

- Sampling
- Ligands
- Novel assays
- Clinical validation
- Sensitive fieldable platform
- Clinical validation

Ability to detect small molecules and amphiphilic pathogen biomarkers, previously undetectable

PATH FORWARD

Clinical Demonstrations

- · Advance assay technology
- Extend technology to other pathogens

Technology Transition

- · Develop for commercial use
- · Develop a single platform for human and veterinary diagnostics

Potential End Users:

· Medical diagnostics and biosensor/biodetection companies

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